K101259 P1/3

3. 510(k) Summary

JUN 17 2010

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: _____

1. Submitter's Identification:

TaiDoc Technology Corporation
3F, 5F, No.127, Wugong 2nd Rd., Wugu Township, Taipei County, 248, Taiwan

Correspondence:
Debra Liang
Regulatory Affairs Specialist
Tel: +886-2-6625-8188
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Prepared date: April 29, 2010

2. Device name:

Proprietary name: V-TRUSTTD-8002 MULTI-PARAMETER SPOT CHECK MONITOR

Regulatory information:

A. Regulation section: 21 CFR 870.2300
B. Classification: Class II
C. Product Code: MWI, monitor, physiological,patient (without arrhythmia detection or alarms)
D. Panel: Cardiovascular

3. Intended Use:

The V-TRUSTTD-8002 Multi-Parameter Spot-Check Monitor measures systolic and diastolic pressure, pulse rate, ear temperature, blood glucose and oxygen saturation of arterial hemoglobin (SpO_2).

- The device is intended to be used by clinicians and medically qualified personnel.
- For glucose measurements, it quantitatively determines glucose levels using capillary and venous whole blood.
- For blood pressure measurements, it is intended to be used to measure noninvasively the systolic and diastolic blood pressure and pulse rate of adults.
- For pulse oximeter measurements, is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate for adults.
- For ear thermometer, it is intended for the intermittent measurement and monitoring human body temperature.

4. Device Description:

The V-TRUST TD-8002 Multi-Parameter Spot-Check Monitor, Model TD-8002 (TD-8002) is a patient monitor that measures and displays real time physiological data of the patient, including blood glucose measurement. The TD-8002 can be used to monitor one or more of the following parameters: Noninvasive blood pressure (NIBP), blood oxygen saturation (SpO2), pulse rate, body temperature, and blood glucose. For all these vital parameters, the TD-8002 will be capable of limit alarms for SpO2, and storing monitoring data for retrospective review.

The TD-8002 has two monitoring devices built in the main unit: oximeter and NIBP monitor. The other two monitoring devices, infra-red ear thermometer and blood glucose meter are connected to the main unit via USB cable. All of the devices for monitoring vital signs are cleared by the FDA.

The oximeter sensor connected to the main unit of TD-8002 is the same as the Solaris Compatible Reusable Adult SpO2 Finger Sensor (Model S100A-090103 or Model S100A-300103) cleared under k061931.

5. Substantial Equivalence Information:

A. Predicate device name and k number:

- 506 Patient Monitor (K051038)
- Oximeter: 503 PULSE OXIMETER (K911124)
- Blood Glucose Meter: Clever Check TD-4231 Blood Glucose Monitoring System (K063212)
- Blood Glucose Test Strip: TaiDoc Pro I Glucose Test Strip (K082169)

- IR Thermometer: Fora ComfortScan Ear Thermometer (K081445)
- NIBP: U-RIGHT TD-3132 Blood Pressure Monitor (K092106)

B. Comparison with predicate:

The V-TRUST TD-8002 Multi-Parameter Spot-Check Monitor has equivalent technological characteristics and the similar intended use as the predicate devices.

6. Test Principle:

The V-TRUST TD-8002 Multi-Parameter Spot-Check Monitor uses the same test principle as the predicate devices.

7. Performance Characteristics:

The laboratory and clinical studies for the performance of V-TRUST TD-8002 Multi-Parameter Spot-Check Monitor demonstrate that the performance of this system meets its intended use and is equivalent to the predicate devices.

8. Conclusion:

Based on the information provided in this submission, the V-TRUST TD-8002 Multi-Parameter Spot-Check Monitor is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JUN 17 2010

Ms. Debra Liang
Regulatory Affairs, Senior Specialist
TaiDoc Technology Corporation
6F, No.127, Wugong 2nd Rd., Wugu Township
Taipei County, Taiwan 24888

Re: K101259
Device Name: V-TRUST Model TD-8002 Multi-Parameter Spot Check Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Patient Physiological Monitor (Without Arrhythmia Detection or Alarms)
Regulatory Class: Class II (Two)
Product Code: MWI
Dated: April 29, 2010
Received: May 4, 2010

Dear Ms. Liang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

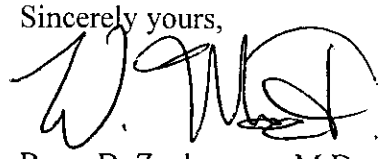
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101259

Indications for Use

510(k) Number: K101259

Device Name: V-TRUST TD-8002 MULTI-PARAMETER SPOT CHECK MONITOR, MODEL TD-8002

Indications for Use:

The TD-8002 Multi-Parameter Spot-Check Monitor measures systolic and diastolic pressure, pulse rate, ear temperature, blood glucose and oxygen saturation of arterial hemoglobin (SpO_2).

- The device is intended to be used by clinicians and medically qualified personnel.
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- For ear thermometer, it is intended for the intermittent measurement and monitoring human body temperature.

Prescription Use __X__ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101259